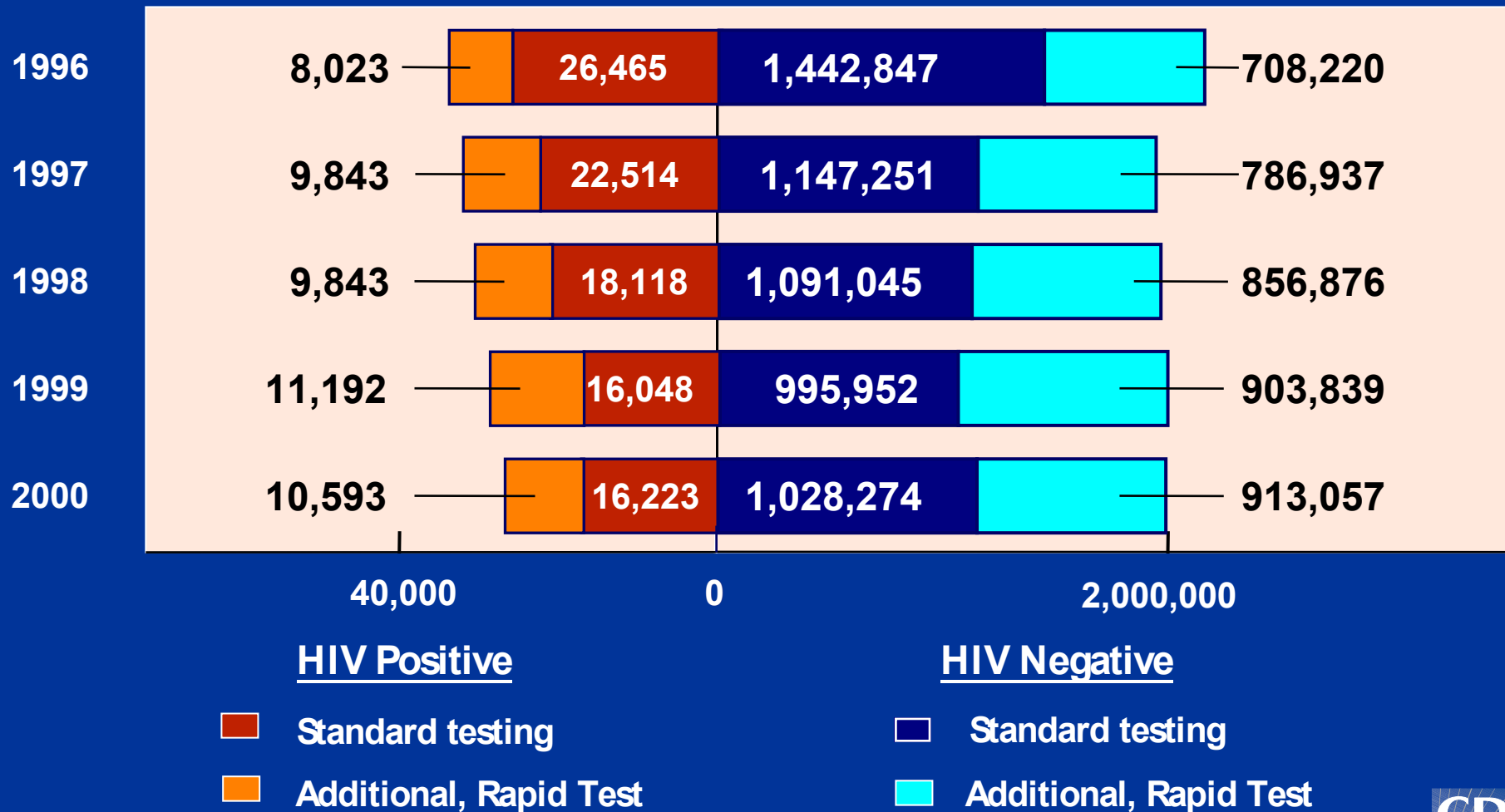


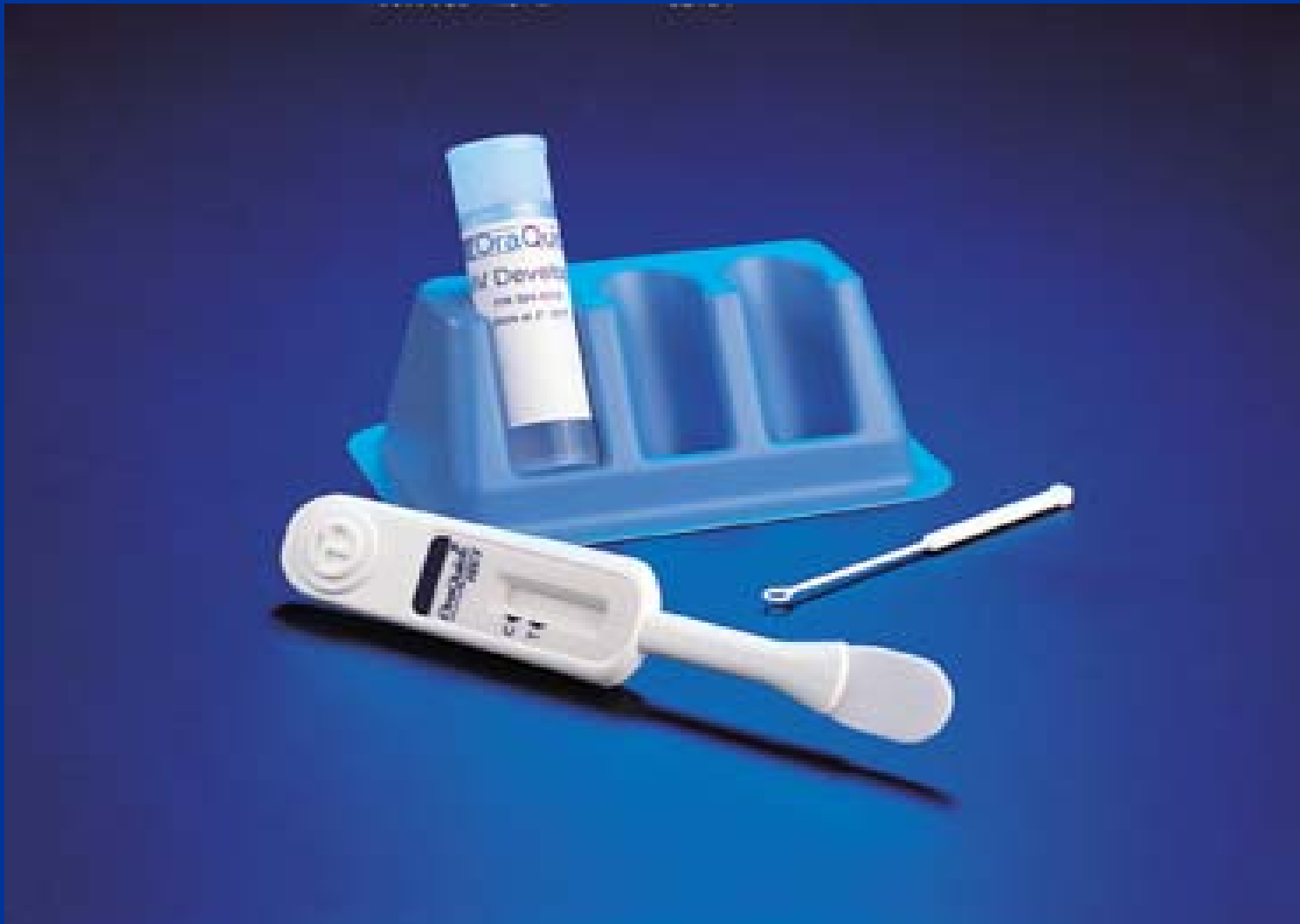
Increasing Our Reach through Rapid HIV Testing

Bernard M. Branson, M.D.

*Chief, Lab Determinants and Diagnostics Section
Centers for Disease Control and Prevention*

What if rapid HIV tests were used in all public testing sites?





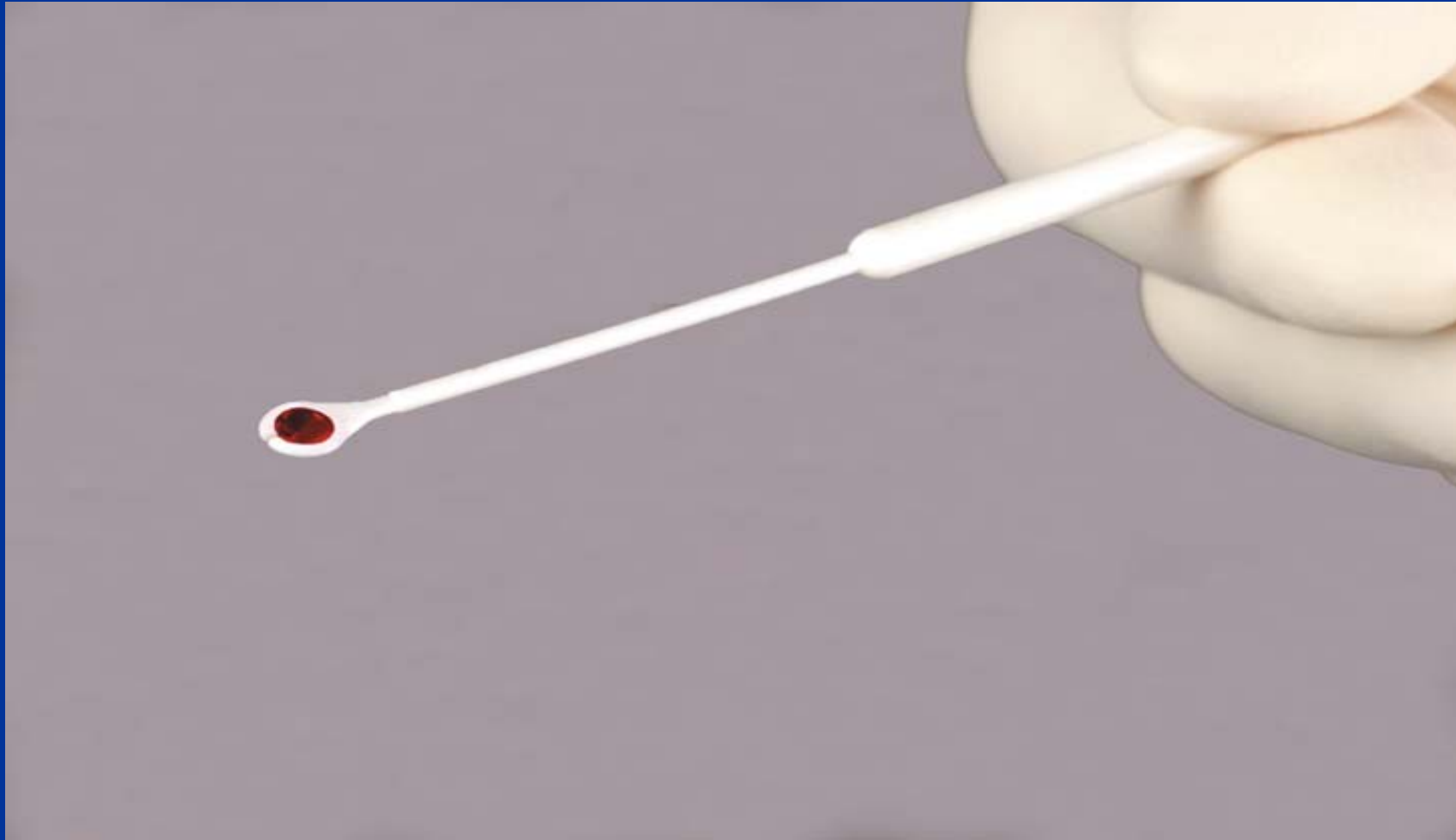
OraQuick: Oral fluid, serum, whole blood



**FDA-approved November 7, 2002 for use
with fingerstick whole blood specimens**



Obtain fingerstick blood specimen



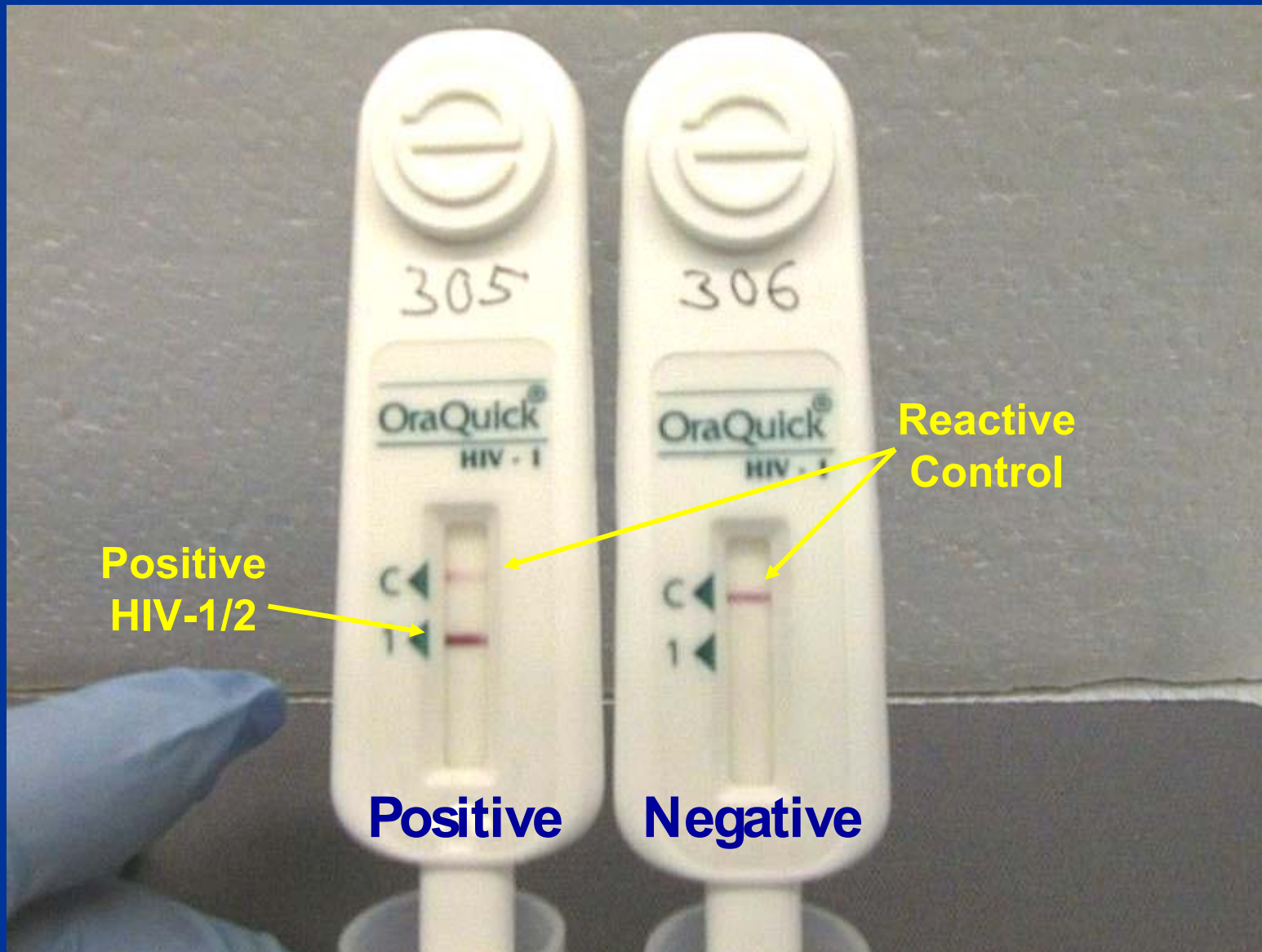
Similar loop is used with several rapid tests



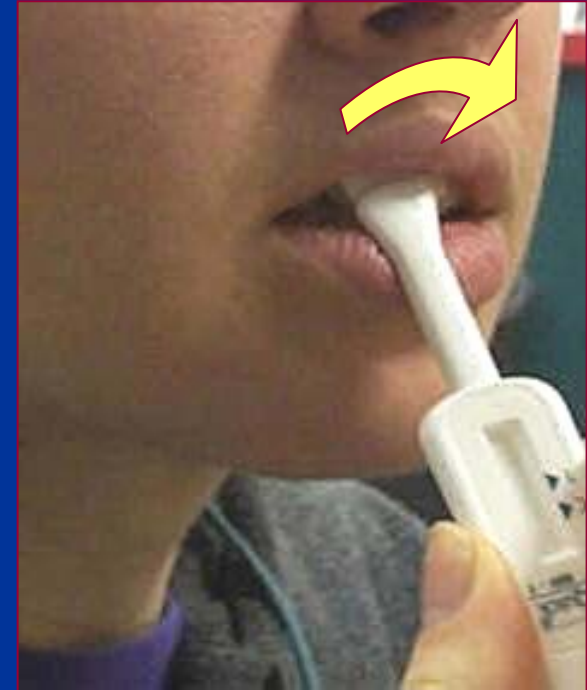
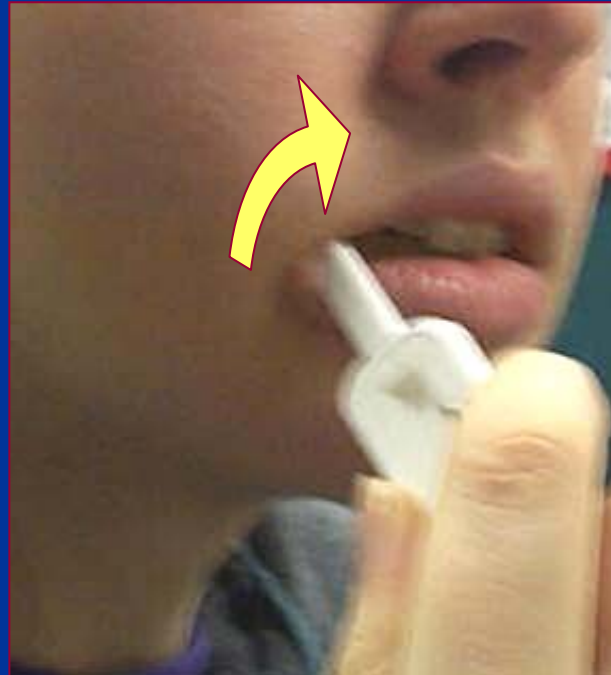
Insert loop into vial and stir



Test develops in 20 minutes



Read results



Oral fluid specimens reduce hazards, facilitate testing in field settings

Rapid Test Performance: Serum

	<u>Sensitivity</u>	<u>Specificity</u>
OraQuick	100%	100%
SUDS	97.9%	94.5%
HIV 1–2 EIA	–	95.1%

206 HIV+, 194 HIV- stored sera

Rapid Test Performance: Prospective Study

	False Negative	Sensitivity	False Positive	Specificity
OraQuick	0/73	100%	2/1639	99.9%
OraQuick Oral	0/72	100%	18/1569	98.9%
SUDS	1/72	98.6%	6/1641	99.6%

1649 Clients at Testing Site /STD Clinics

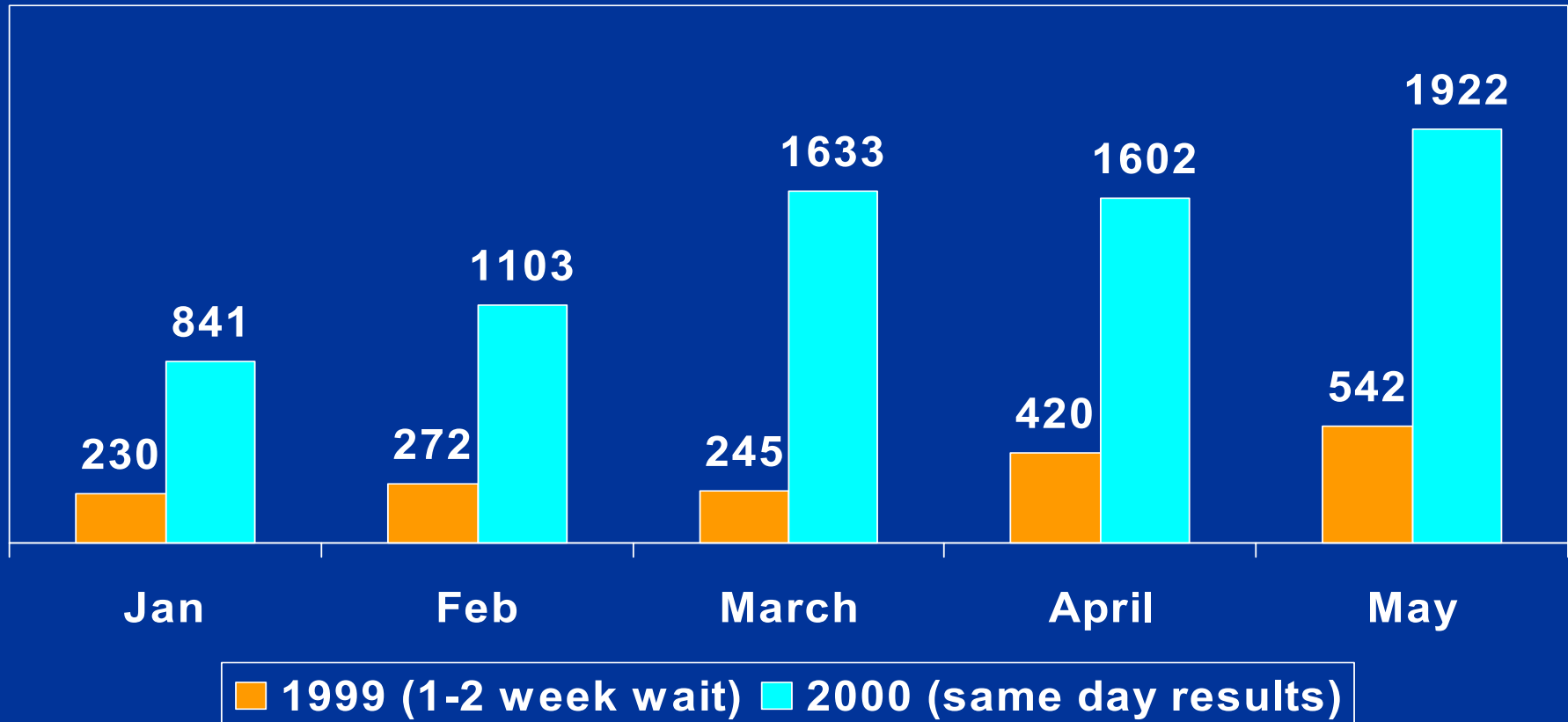
CDC experiences with rapid HIV testing outside the US

HIV Testing in Kenya is Done on Site by a Trained Counselor, Supervised by a Laboratory Technician

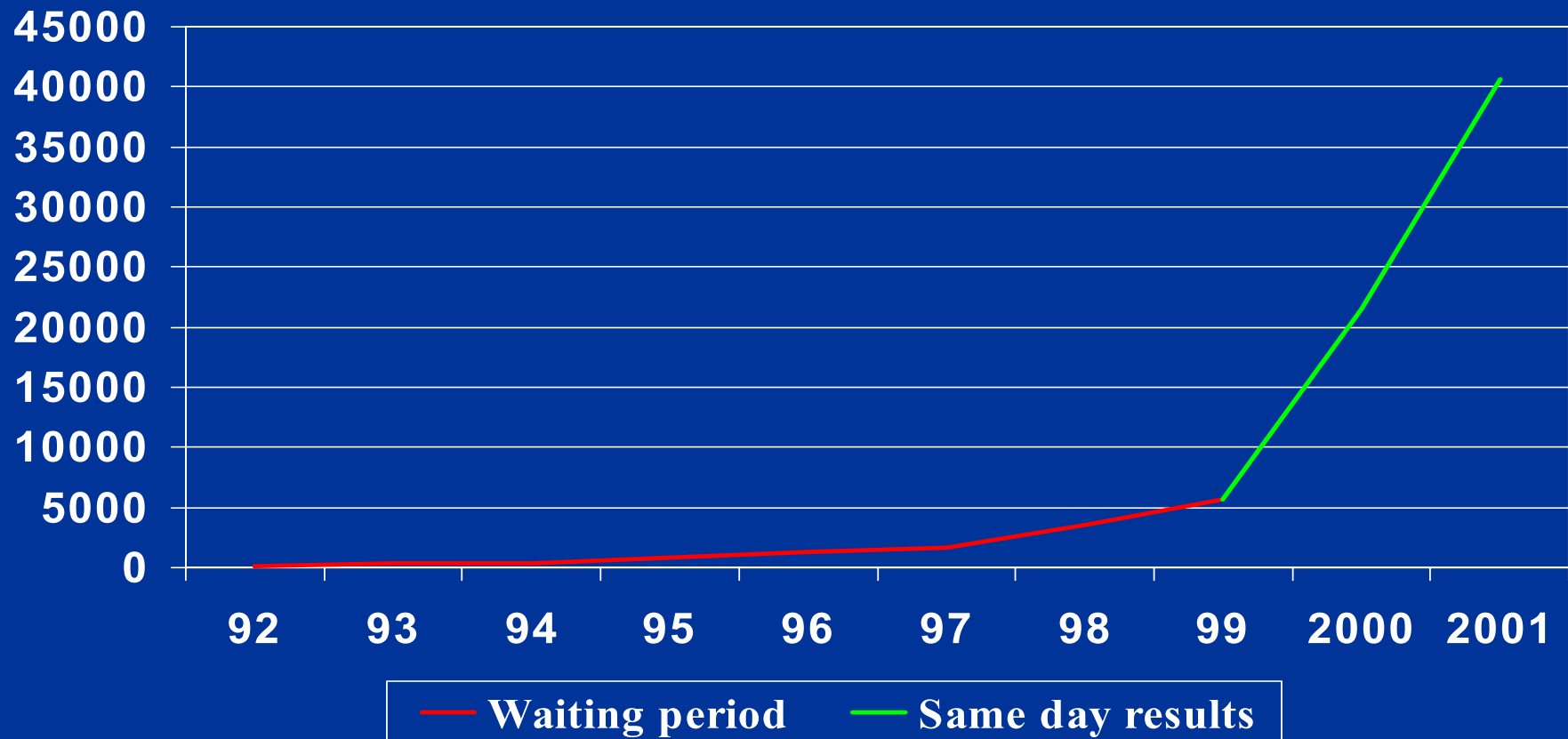


- Two different, rapid, simple whole blood tests are used for every client
- Confirmed results in 15 to 20 minutes
- Tests used at present:
 - Abbott Determine
 - Trinity Biotech UniGold

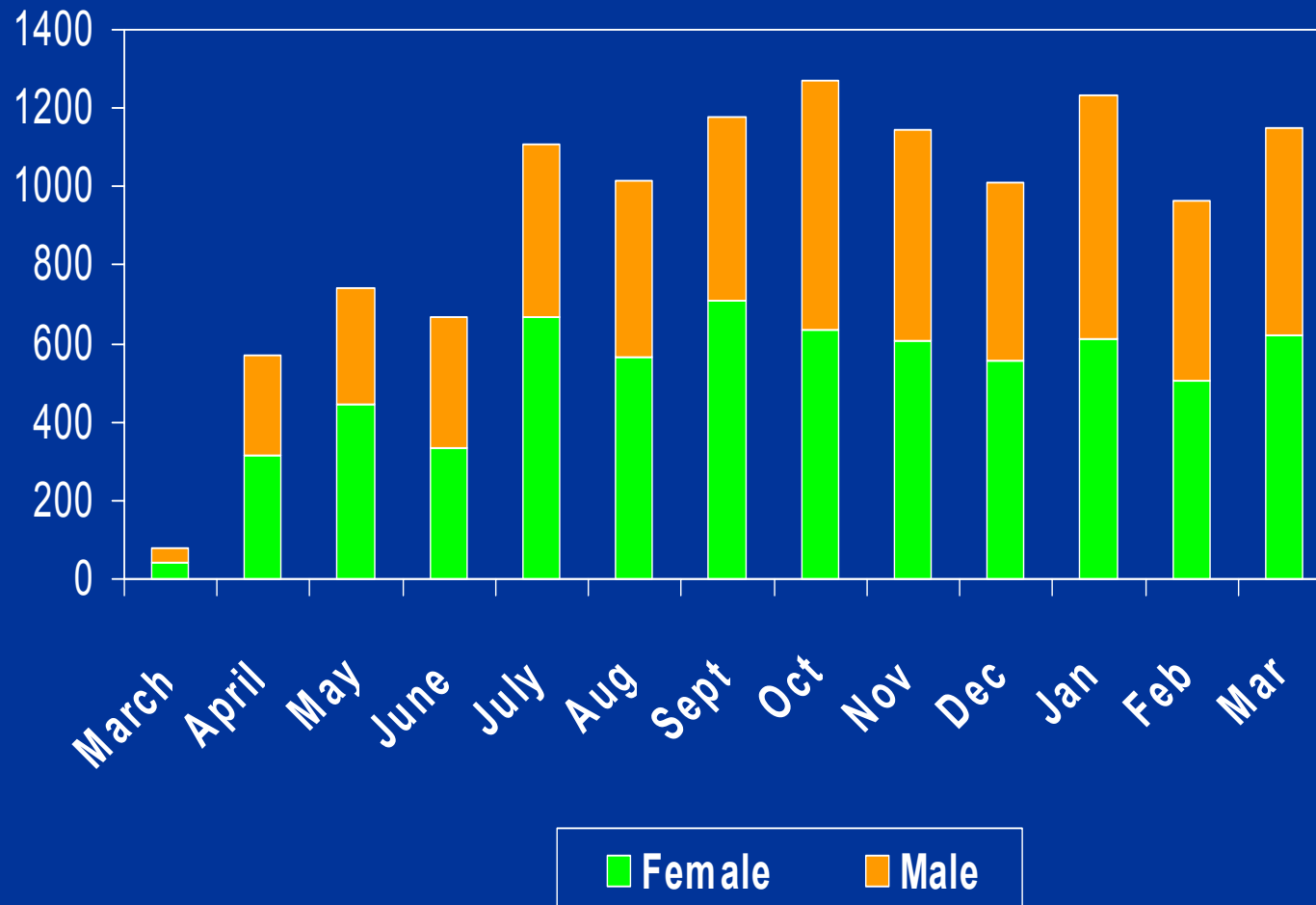
Increase in Demand for VCT in Malawi with Same Day Results using Rapid Tests



VCT Clients in Malawi: Waiting period versus same day results



Rapid Increase in Utilization of VCT in Kibera, March 2001 – March 2002



- KICOSHEP served 12,157 VCT clients at 5 sites in the Kibera slum and at 17 medical camps

Outcomes with rapid HIV testing in the U.S.

Cook County Jail (CCJ)

Female Intake

- Largest single-site jail in the U.S.
- 100,000 detainees each year
- 15% females:
 - 80+ females through intake area daily
 - 50% released in ≤ 36 hours
- Study period: October 2000 – May 2001

Cook County Hospital Emergency Department (CCH-ED)

- Busiest emergency department in Chicago
- 120,000+ patient visits per year
- January 2001 conventional HIV testing
- Study period: June 2001 – February 2002

Eligibility and Acceptance

	CCJ Intake	CCH -ED
# Approach	3055	7072
# Eligible	2289 (75%)	6038 (85%)
# Accept RT	988 (43%)	1652 (27%)

Rapid Test Outcomes

	CCJ Intake	CCH ED
# rapid tested	988	1652
# received results	985 (99.7%)	1640 (99.3%)
# new HIV+	9 (0.9%)	46 (2.8%)
# entered care	2 (22%) median 50 days	36 (80%) median 13 days

Characteristics

Rapid Test Positive Patients

	CCJ <i>N=9</i>	CCH <i>N=46</i>
No previous test	4 (44%)	26 (57%)
Risk Factors		
MSM	0	14 (30%)
IDU	1 (11%)	6 (13%)
Sex Partner IDU	0	3 (7%)
Sex Partner HIV+	0	3 (7%)
No identified risk	2 (22%)	22 (48%)

Surprises

CCJ – Female Intake

- None of RT patients came to Screening Clinic for CT results
- Difficulties in patient follow-up

CCH – ED

- Many HIV+ patients without risk factors
- Second phlebotomy not a deterrent
- Many patients had no additional blood drawn
- Little need for psych support

HIV Screening in Acute Care Settings

	<u>New HIV+</u>
■ Cook County ED, Chicago	2.8%
■ Grady ED, Atlanta	2.7%
■ Johns Hopkins ED, Baltimore	3.2%

Perinatal Screening: MIRIAD Study

- Testing of pregnant women in labor for whom no HIV test results are available; 12 hospitals in 5 cities: Atlanta, Chicago, Miami, New Orleans, New York
- To date
 - 1771 women screened
 - 12 new HIV infections identified
 - No false positives, no false negatives

Bethany Hospital

- Rapid test performed on Labor and Delivery unit.
- Eligible patients are determined here in the Labor and Delivery Triage area.



Provident Hospital



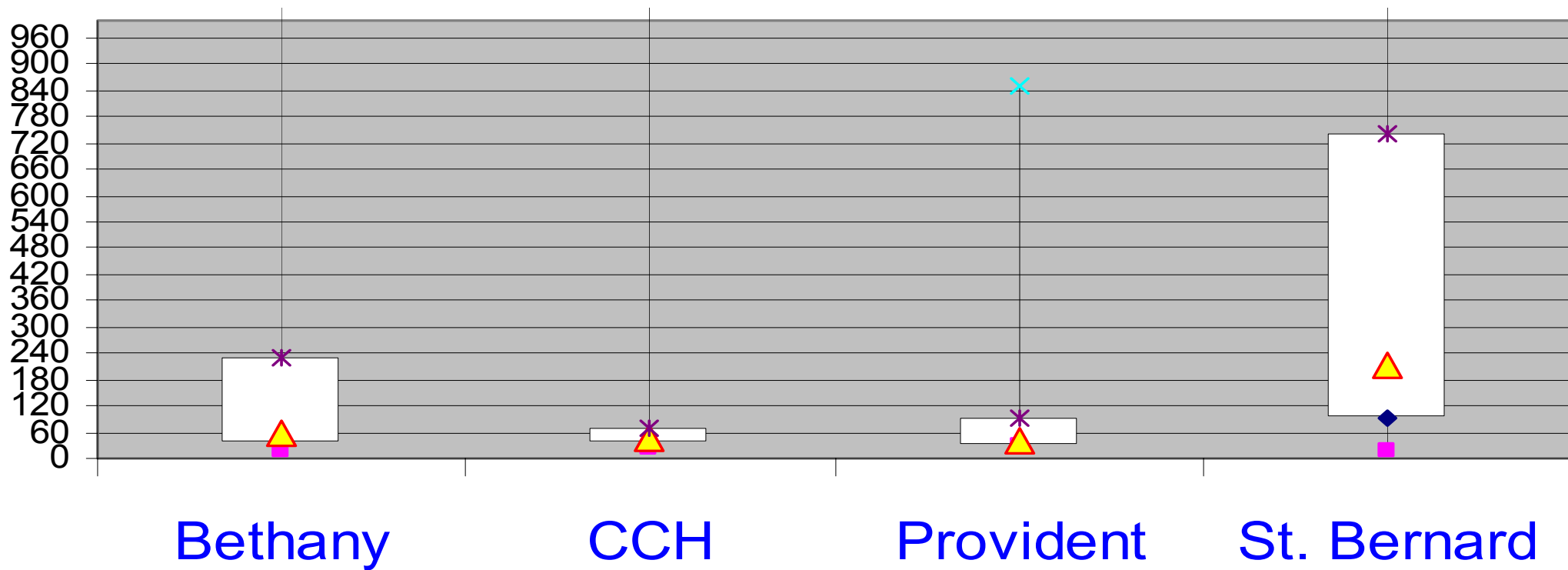
- The rapid test is done on this counter, extra supplies are stored below.
- OB physicians and Midwives share MIRIAD testing at Provident.

Cook County Hospital

- Clerks on each shift access HIV results from the computer system.
- Eligible patients are offered rapid testing and consented in the Triage area.



Boxplot of Turn Around Times



Reasons for Delay in Delivering Rapid Test Results

- Out of sight out of mind (when sent to lab)
- Shift change
- Patient sleeping
- Getting blood to the laboratory and getting result back

OraQuick Outreach to High Risk Persons of Color

Patrick Keenan MD

University of Minnesota Medical School

**Department of Family Practice and
Community Health**

OraQuick Research Study

(7/22/02) N = 115

- On-site group pretest counseling.
- Individual testing and post-test counseling.
- Testing procedure:
 - Oral fluid OraQuick (research only)
 - Fingertick OraQuick (results given)
 - Fingertick neg -> OraSure backup
 - Fingertick pos -> venous EIA/WB

Client Survey Results I

- “I have tested for HIV in the past and I prefer receiving my results the same day”

Strongly agree or agree = 97%

Disagree or strongly disagree = 3%

Client Survey Results II

- “It would have been better to wait a week before getting any results”

Agree or strongly agree = 3%

Disagree or strongly disagree = 97%

Client Survey Results III

- “I found the rapid testing stressful”

Agree or strongly agree = 33%

Disagree or strongly disagree = 67%

Client Survey Results IV

- “I would rather have my finger stuck than have blood drawn from my vein”

Agree or strongly agree = 88%

Disagree or strongly disagree = 7%

No difference = 5%

Client Survey Results V

- **“I would recommend rapid testing to a friend”**

Agree or strongly agree = 94%

Disagree or strongly disagree = 6%

Client Survey Results: VI

- “I understand the results of my test.”

Agree or strongly agree = 99%

Disagree or strongly disagree = 1%



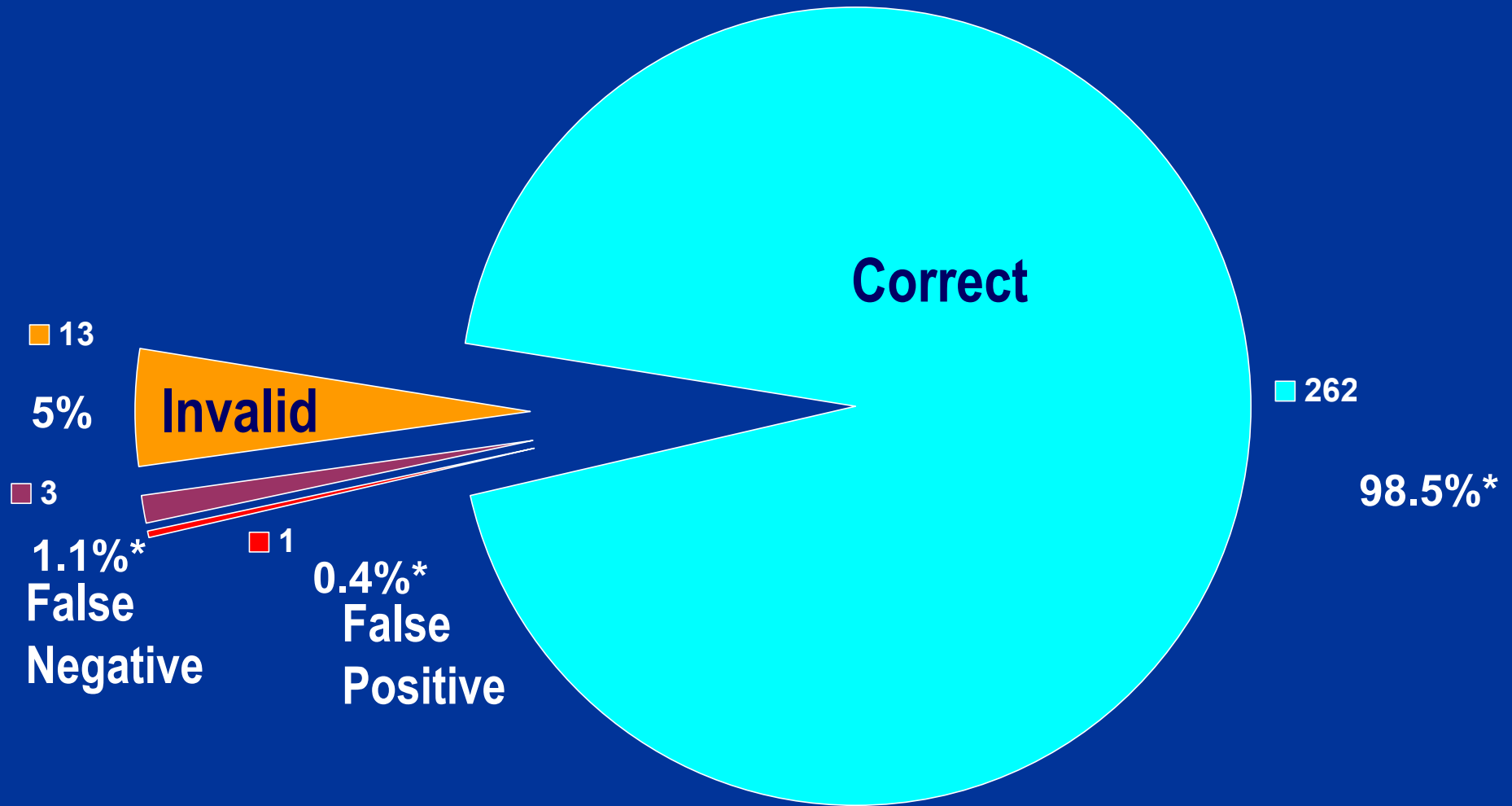
GAY & LESBIAN CENTER



STD CLINIC

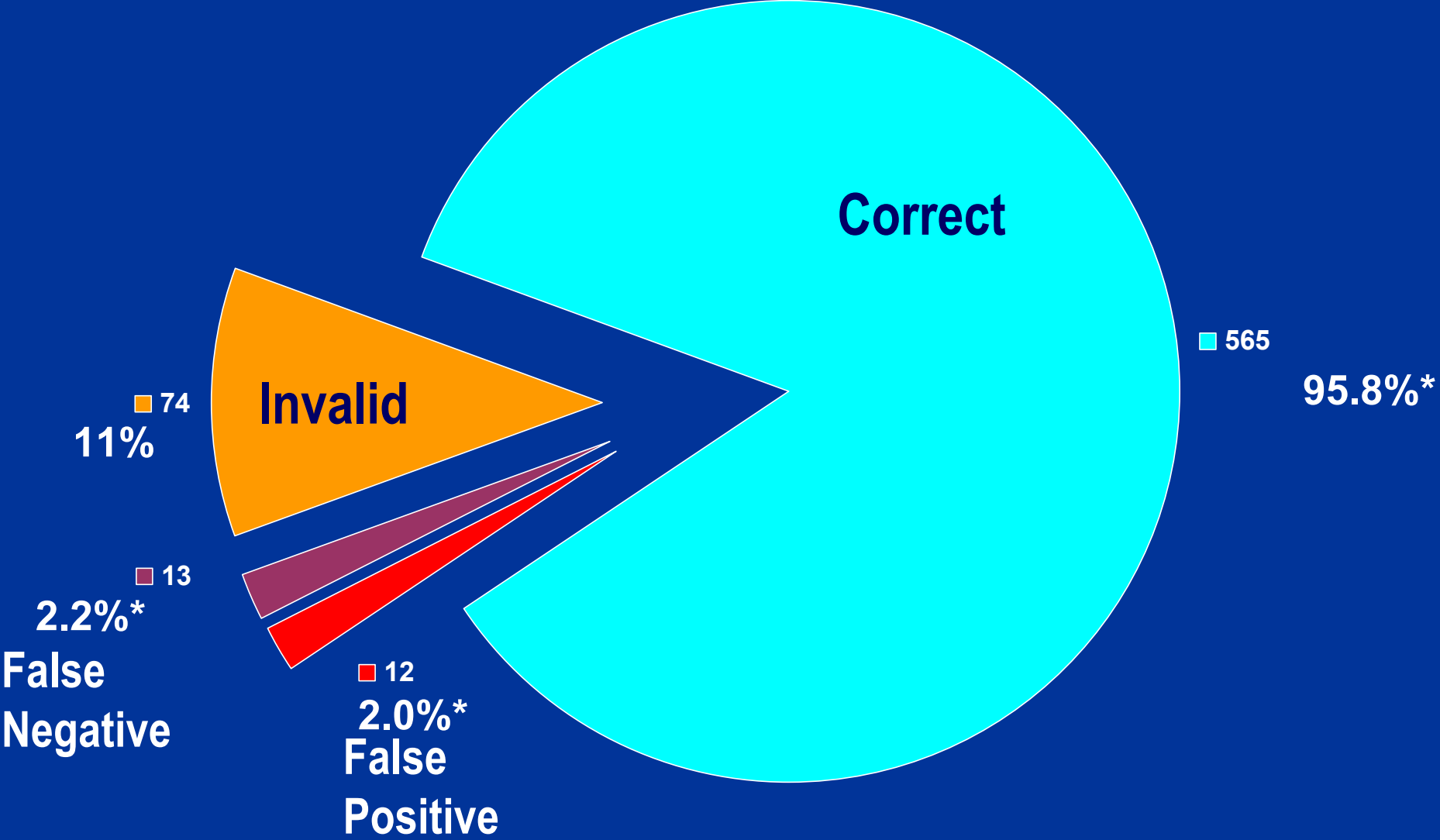


Untrained Users 1– 279 Patient specimens



*Percentage of correct results obtained, does not include 13 “invalid” test results.

Untrained Users – 664 Evaluation panel specimens



*Percentage of correct results obtained, does not include 74 “invalid” test results.

Lessons Learned

- **Client Acceptance Levels**
- **Testing & Counseling Unit Logistics**
- **Personnel Issues**

Confirmatory Testing

- For Western blot:
 - Venipuncture for whole blood
 - Oral fluid specimen
 - Dried blood spots on filter paper